

YAHORNG

Ya Horng CO., LTD.

No. 35, Zsha Lun, Jon Zsha village,
Antin Shiang, Tainan, Taiwan, ROC

Tel: 886-6-5932201 Fax: 886-6-5935870

E-mail: lab@yahorng.com http:// www.yahorng.com

AUG 5 - 2005

K051539
page 1 of 1

3. SUMMARY OF SAFETY AND EFFECTIVENESS

(According to 21 CFR 807.92)

DATE OF

SUBMISSION:

May 22, 2005

SUBMITTER:

General Manager, Mr. HSU, SHENG HSIUNG
YA HORNG ELECTRONIC CO., LTD.

No 35, Zsha Lun

Jon Zsha Village,

Antin Shiang, Tainan, CHINA (TAIWAN) 745

TEL: 886-6-5932201

FAX: 886-6-5935870

ESTABLISHMENT

REGISTRATION NO:

3001147827

OFFICIAL

CONTACT:

Dr. JEN, KE-MIN

ROC CHINESE-EUROPEAN INDUSTRIAL RESEARCH
SOCIETY

NO 58, FU-CHIUN ST.

HSIN-CHU CITY, CHINA (TAIWAN) 30067

TEL: 886-3-5208829

FAX: 886-3-5209783

TRADE NAME:

TRICOT BLOOD PRESSURE CUFF

COMMON/USUAL

NAME:

BLOOD PRESSURE CUFF

CLASSIFICATION

NAME:

CUFF, BLOOD PRESSURE (CFR870.1120)

CLASSIFICATION

PANEL:

CARDIOVASCULAR

PREDICATED

DEVICE:

KTJ-20C GOLDEN HORSE MEDICAL EQUIPMENT
(K010686)

INTENDED USE:

The TRICOT blood pressure cuff is used in conjunction with non-invasive blood pressure measurement systems by personnel properly trained. The device is non-sterile and is intended as a reusable multi-patient device for measuring one's blood pressure. It is available in child through large adult sizes



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 5 - 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ya Horng Electronic Co.,Ltd.
c/o Dr. Jen Ke-Min
Official Correspondent
No.35, Zsha Lun, Jon Zsha Village
Antin Shiang, Tainan,
China Taiwan, 745

Re: K051539

Trade Name: Ya Horng Blood- Pressure Cuff, Tricot
Regulation Number: CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II (two)
Product Code: DXQ
Dated: June 6, 2005
Received: June 10, 2005

Dear Dr. Ke-Min:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

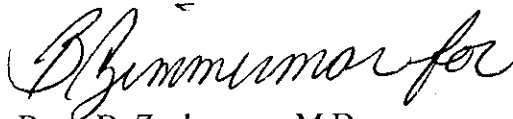
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 - Mr. Shu-Mei Wu

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0295. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "B. Zuckerman for".

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

YAHORNG

Ya Horng CO., LTD.

No. 35, Zsha Lun, Jon Zsha village,

Antin Shiang, Tainan, Taiwan, ROC

Tel: 886-6-5932201 Fax: 886-6-5935870

E-mail: lab@yahoo.com http:// www.yahorng.com

2. INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number:

TBA K051539

Device Name:

YA HORNG ELECTRONIC CO., LTD.
BLOOD-PRESSURE CUFF, TRICOT

INTENDED USE

The TRICOT blood pressure cuff is used in conjunction with non-invasive blood pressure measurement systems by personnel properly trained. The device is non-sterile and is intended as a reusable multi-patient device for measuring one's blood pressure. It is available in child through large adult sizes.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bhimmanna
(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K051539